

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Ho on 9/22/10.

Claims:

1. (Currently amended): A device for diagnostic NO measurements, the device comprising:
  - a combined inlet and outlet configured to provide NO-scrubbed inhalation air to a patient and to accept an exhalation air at an exhalation flow rate;
  - a NO scrubber connected to the combined inlet and outlet along an inhalation flow path, the NO scrubber configured to provide NO-scrubbed air to the combined inlet and outlet;
  - a buffer chamber connected to the combined inlet and outlet along an exhalation flow path, the buffer chamber configured to temporarily hold a sample of the exhalation air for a period of time;
  - a flow regulator positioned between the combined inlet and outlet and the buffer chamber, the flow regulator configured to control the exhalation flow rate to 20 - 800 ml/s;
  - an electrochemical NO sensor connected to the buffer chamber, the electrochemical sensor configured to receive the sample of exhalation air temporarily held by the buffer chamber; and

- means for feeding the temporarily held sample of the exhalation air from the buffer chamber to the electrochemical NO sensor at a suitable flow rate for the electrochemical NO sensor, wherein the suitable flow rate for the electrochemical NO sensor is lower than the exhalation flow rate.

2. (Cancelled)
3. (Previously presented): The device according to claim 1, wherein the suitable flow rate for the electrochemical NO sensor is about 0.5 to 15 ml/s.
4. (Previously presented): The device according to claim 1, wherein the device comprises means for equalizing the humidity of the sample.
5. (Previously presented): The device according to claim 4, wherein said means for equalizing the humidity of the sample comprises a length of tube, made from a catalytic membrane material.
6. (Previously presented): The device according to claim 1, wherein the device further comprises control electronics for verifying the parameters of the inhalation and controlling the parameters of exhalation.
7. (Previously presented): The device according to claim 6, wherein said control electronics comprise a pressure sensor and means for giving feedback to the patient.
8. (Previously presented): The device according to claim 6, wherein said control electronics further comprise a flow sensor and means for controlling the flow and/or giving feedback to the patient.
9. (Previously presented): The device according to claim 6, wherein said control electronics further comprise a pressure sensor capable of measuring absolute pressure in order to make it possible to compensate for varying partial pressure of NO depending on variations in ambient pressure.

10. (Cancelled)

11. (Previously presented): The device according to claim 1, wherein the buffer chamber comprises a cylinder with a movable piston.

12. (Previously presented): The device according to claim 1, wherein the buffer chamber comprises a length of tube.

13. (Cancelled)

14-18 (Cancelled)

19. (Currently amended): A method for diagnostic NO measurements, the method comprising the steps of:

a patient inhales through an inhalation flow path of a device comprising a flow regulator, an electrochemical NO sensor, a NO scrubber, and a buffer chamber,

said patient exhales air into an exhalation flow path of said device, wherein an exhalation flow rate and pressure is controlled to a preset value between 20 - 800 ml/s by the flow regulator,

a sample of the exhaled air from said patient is temporarily held for a period of time in said buffer chamber,

said sample is fed to said electrochemical NO sensor at a flow rate lower than the exhalation flow rate, and

an NO concentration is determined in said sample.

20. (Original): A method according to claim 19, wherein the patient inhales NO-free air prior to exhaling into the device.

- 21.(Previously presented): A method according to claim 19, wherein the patient inhales through the NO-scrubber integrated in said device, supplying NO-free air to the patient, prior to exhaling into the device.
- 22.(Original): A method according to claim 19, wherein the patient is given audible or visual feedback during the inhalation and exhalation steps, in order to support the correct performance of said steps.
- 23.(Currently amended): A method according to claim 19, wherein ~~the exhalation flow rate is controlled to a value of about 20 to 800 ml/s and the rate at which the sample is fed to the sensor is about 0.5 to 15 ml/s.~~
- 24.(Cancelled)
- 25.(Cancelled).
- 26.(Previously presented): A method according to claim 19, wherein the device comprising an electrochemical NO sensor further comprises a user interface, wherein at least one of the following steps is included:
  - the patient enters information relating to his/her intake of a medicament into the user interface; and
  - the patient subjectively assesses his/her state of health and enters corresponding information into the user interface.
- 27.(Previously presented): A computer program comprising instructions for performing the method according to claim 19, wherein the instructions are stored in a computer-readable medium.
- 28.(Cancelled).
- 29.(Previously presented): A method for diagnostic determination of NO in a gas sample, the method comprising the steps of:

introducing a sample at a first flow rate into the device of claim 1;  
storing said sample in the buffer chamber temporarily;  
feeding said sample to the electrochemical NO sensor at a second flow rate;  
wherein the first flow rate is higher than the second flow rate.

30.(Currently amended): The device according to claim [[2]] 1, wherein the flow regulator is configured control the flow rate of the exhalation air to the buffer chamber at a rate of 45-55 ml/s.

31.(Cancelled)

32.(Currently amended): The device of claim 1, further comprising an ambient air inlet connected to the NO scrubber, wherein the ambient air inlet and the combined inlet and outlet are separate structures.

33.(Cancelled)

34.(Cancelled)

35.(Cancelled)

2. The following is an examiner's statement of reasons for allowance: In addition to the remarks of record, the cited prior art fails to teach or suggest the claimed method or apparatus comprising a flow regulator that controls the exhalation flow rate to 20-800 ml/s. The closest prior art, Mault (USP 6,468,222), teaches in column 11 lines 58-67 the average flow rate is 0.045ml/s. There is not motivation known or of record to modify Mault to include the claimed flow regulator that controls the exhalation flow rate to 20-800 ml/s.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYLE A. ALEXANDER whose telephone number is (571)272-1254. The examiner can normally be reached on Monday though Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LYLE A ALEXANDER/  
Primary Examiner, Art Unit 1797